K130464
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Carestream

JUN 0 7 2013

"510(k) Summary"

510(k) Owner Name:	Carestream Health, Inc.
510(k) Owner Address:	150 Verona Street Rochester, New York 14608
510(k) Owner Phone:	585 627-6543
510(k) Owner Fax:	585 454-1894
Contact Person & Info:	Carolyn Wagner Regulatory Affairs Manager, X-ray Solutions carolyn.wagner@carestream.com 585-627-6588
Date Summary Prepared:	February 18, 2013
Device Trade Name:	Carestream DRX-1 System w/ DRX 2530C Detector
Device Common Name:	Flat Panel Digital Imager
Classification Name:	Solid State X-Ray Imager (Flat Panel/Digital Imager)
Device Class:	Class II
Device Code:	MQB
Regulation Number:	21 CFR 892.1650
Predicate Device:	Carestream DRX-1 System (w/ DRX-1 Detector) Manufactured by Carestream Health, Inc. 510(k) No. – K090318 (April 6, 2009)

Device Description:

The Carestream DRX-1 System is a diagnostic imaging system utilizing digital radiography (DR) technology that is used with diagnostic x-ray systems. The system consists of the Carestream DRX-1 System Console (operator console), flat panel digital imager (detector), and optional tether interface box. The system can operate with either the Carestream DRX-1 System Detector (GOS) or the DRX-2530C Detector (CsI) and can be configured to register and use both detectors. Images captured with the flat panel digital detector can be communicated to the operator console via tethered or wireless connection.

Indications for Use / Intended Use:

The Indications for Use for the device, as described in its labeling, are:

"The device is intended to capture for display radiographic images of human anatomy including both pediatric and adult patients. The device is intended for use in general projection radiographic applications wherever conventional screen-film systems or CR systems may be used. Excluded from the indications for use are mammography, fluoroscopy, and angiography applications."

The intended use for this device, as determined by descriptions and the proposed labeling contained in this submission, is similar to the Indications for Use statement provided above. The Carestream DRX-1 System with DRX 2530C Detector is a diagnostic imaging system utilizing digital radiography (DR) technology that is used to capture x-rays for diagnostic procedures. We believe that the Carestream DRX-1 System with DRX 2530C Detector and the predicate device have the same intended use.

The Indications for Use for the subject device is different than the predicate device, but these differences do not alter the intended diagnostic use of the device. Differences are appropriately characterized as descriptive, and the intended use remains unchanged. Any variation in features or technical specifications have been identified and addressed through testing (described below) to support a substantial equivalence determination.

Comparison of Technological Characteristics:

Based upon information provided within this submission, we believe that the Carestream DRX-1 System with DRX 2530C Detector is substantially equivalent to the legally marketed Carestream DRX-1 System with DRX-1 System Detector (predicate device). Both the currently marketed DRX-1 Detector and the new DRX 2530C Detector are used in combination with the image processing software and user interface resident on the DRX-1 System Console component of the Carestream DRX-1 System. Both systems are used to directly capture and convert conventional projected x-ray images to generate digital images. An image can be displayed on a preview monitor for viewing with either detector. Both systems can transmit diagnostic images through a digital network for diagnostic viewing and printing.

The DRX 2530C Detector is a new component that can be used with the Carestream DRX-1 System. The DRX 2530C Detector is physically smaller than the Carestream DRX-1 System Detector and therefore has a smaller active image area. It is specifically designed to image smaller body parts and to function easily in confined locations. The DRX 2530C has functional and performance enhancements over the DRX-1 Detector such as a handle, a 16 bit dynamic range, and increased fluid resistance. These enhancements are designed to aid the user in achieving an efficient workflow.

The differences between the Carestream DRX-1 System with DRX 2530C Detector and the predicate device (Carestream DRX-1 System with DRX-1 System Detector) do not affect the intended use of the device or alter the fundamental scientific technology of the device.

Discussion of Testing

The performance characteristics and operation / usability of the Carestream DRX-1 System with DRX 2530C Detector were evaluated in non-clinical (bench) testing. These studies have demonstrated the intended workflow, related performance, overall function, shipping performance, verification and validation of requirements for intended use, and reliability of the system including both software and hardware requirements. Non-clinical test results have demonstrated that the device conforms to its specifications. Predefined acceptance criteria were met and demonstrated that the device is as safe, as effective, and performs as well as or better than the predicate device.

A concurrence study of clinical image pairs was performed in accordance with FDA guidance document "Guidance for the Submission of 510(k)'s for Solid State Imaging Devices" to demonstrate the diagnostic capability of the Carestream DRX-1 System with DRX 2530C Detector. Results of the Reader Study indicated that the diagnostic capability of the Carestream DRX-1 System with DRX 2530C Detector is statistically equivalent to or better than that of the predicate device. These results support a substantial equivalence determination.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 7, 2013

Carestream Health, Inc.
% Ms. Carolyn L. Wagner
Regulatory Affairs Manager
150 Verona Street
ROCHESTER NY 14608

Re: K130464
Trade/Device Name: Carestream DRX-1 System
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: May 8, 2013
Received: May 9, 2013

Dear Ms. Wagner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130464

Device Name: Carestream DRX-1 System

Indications for Use:

The device is intended to capture for display radiographic images of human anatomy including both pediatric and adult patients. The device is intended for use in general projection radiographic applications wherever conventional screen-film systems or CR systems may be used. Excluded from the indications for use are mammography, fluoroscopy, and angiography applications.

Prescription Use __X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostic and Radiological Health

510(k) K130464